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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,670	03/19/2001	Akiko Itai	P20797	9032
7055 7590 09/12/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER DEJONG, ERIC S	
			ART UNIT 1631	PAPER NUMBER
			NOTIFICATION DATE 09/12/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

# Office Action Summary

Application No.

09/810,670

Applicant(s)

ITAI ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06/14/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,6,7 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,7 and 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 06/14/2007 and 07/20/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED OFFICE ACTION**

This application has been transferred to a new Examiner.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/14/2007 has been entered.

Claims 2-5 and 8-10 are cancelled. Claims 1, 6, 7, and 11-13 are pending and currently under examination.

### ***Information Disclosure Statement***

The references cited in the Information Disclosure Statements filed 06/14/2007 and 07/20/2007 have been considered in full.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 6, 7, and 11-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 6, 7, and 11-13 are drawn to a method for selecting at least one lead-candidate compound capable of binding as a ligand to a protein. The method comprises the abstract/computational steps of inputting at least one query molecule known to bind, or is expected to bind, the protein, in silico screening of lead candidate compounds, and outputting at least one lead-candidate compound and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation that results from said application of judicial exception, thus the Examiner must determine if said application of a judicial exception produces a useful, concrete, and tangible result.

In determining if the application of a judicial exception produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a result to be "useful," the application of a judicial exception must produce a result

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that is specific, and substantial. For a result to be "concrete," the application of a judicial exception must have a result that is reproducible. For a result to be "tangible," the application of a judicial exception must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1, 6, 7, and 11-13 do not produce a tangible result. It is acknowledged that the instant claims have been amended to recite an "outputting" step (see line 13 of claim 1), however this step is not limited to an "output" in a tangible form useful to one performing method. A tangible result requires that the claim must set forth a practical application of a judicial exception to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the application of a judicial exception is outputted to a display, a user, a readily accessible memory or other computer on a network, or by including a physical transformation that results from the recited application of a judicial exception.

***Claim Rejections - 35 USC § 112, First paragraph***

The rejection of claims 1, 6, 7, and 11-13 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of applicants arguments and amendments made to the instant claims.

***Claim Rejections - 35 USC § 112, Second paragraph***

The rejection of claims 1, 6, 7, and 11-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicants arguments and the amendments made to the instant claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 7 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (IDS ref: J. Med. Chem. (1994) vol. 37, pp. 4479-4489). This rejection is maintained from the Office action mailed 12/15/2006.

The instant claims are drawn to a method for selecting at least one lead-candidate compound capable of binding as a ligand to a protein. The claimed method comprises the steps of inputting at least one query molecule known to bind or expected to be bound by the protein, screening lead-candidate compounds from a compound database by matching modes of covalent bonds between a query and trial compounds and judging similarities of partial structures of said compounds based on two-dimensional graphs, and outputting at least one lead-candidate compound capable of binding the protein.

Wang et al. discloses a computer protein kinase C (PK-C) pharmacophore search on 206,876 nonproprietary structures in the NCI 3D-database that led to the discovery of five compounds which were found to possess PK-C binding affinities (see Wang et al., Abstract). Wang et al. disclose the construction of a PK-C pharmacophore query used in the 3D-database pharmacophoric search (see Wang et al., Figure 1) which is known to bind the PK-C receptor (see Wang et al., page 4480 col. 1, lines 1-17). The results of the computer implemented 3D-database pharmacophore search resulted in the identification of 535 that sufficiently matched the PK-C pharmacophore (see Wang et al., page 4480, col. 1, line 18 through col. 2, line 66). Wang et al. further disclose the visual inspection of 286 compounds of the 535 identified matches for the presence of hydrophobic constituents and further displays the 2D structures of 11 of said 286 compounds wherein atoms and covalent bonds are presented (see Wang et al., Figure 2 and page 4480, col. 2, lines 52-66). Wang et al. further disclose the computational molecular modeling study of known PK-C agonists containing a hydrophobic moiety and the use of this information in the qualitative selection of the final 125 compounds (see Wang et al., page 4480, col. 2, line 46-51 and page 4481, col. 2, line 1 through page 4486, col. 2, line 38). Wang et al. further discloses the synthesis and binding affinity testing of 125 identified compounds (see page 4481, col. 1, lines 1-12).

***Response to Arguments***

Applicant's arguments filed 06/14/2007 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC § 101 as being directed to non-statutory subject matter, applicants argue that the instant claims have been amended to address any alleged §101 deficiencies.

In response, it is reiterated from the above rejection that the amendment to claim 1 so as to recite an "outputting" step (see line 13 of claim 1) does not limit what is "output" to tangible form. A tangible result requires that the claim must set forth a practical application of a judicial exception to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the application of a judicial exception is outputted to a display, a user, a readily accessible memory, or by including a physical transformation that results from the recited application of a judicial exception.

In regards to the rejection of claims under 35 USC § 102(b) as being anticipated by Wang et al., applicants argue that Wang et al. does not judge the similarity of query molecules "based on two-dimensional graphs of the query molecule and the trial compound where each atom is represented as a node and each covalent bond is represented as an arc".

In response, it is reiterated from the above rejection that the pharmacophore query (partial structure) was used to identify matching structures from the NCI



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compound database, perform the visual inspection of 286 compounds of the 535 identified matches for the presence of hydrophobic constituents, and in further displays the 2D structures of 11 of said 286 compounds wherein atoms and covalent bonds are present. Therefore, Wang et al. anticipates the limitation drawn judging similarity of partial structures based on 2D graphs a query molecule and trial compounds. It is further noted that the 2D structures of compounds presented in Figure 2 (those that were visually inspected) comprise nodes representing atoms and arcs representing covalent bonds. Therefore, applicants argument is not persuasive.

### ***Conclusion***

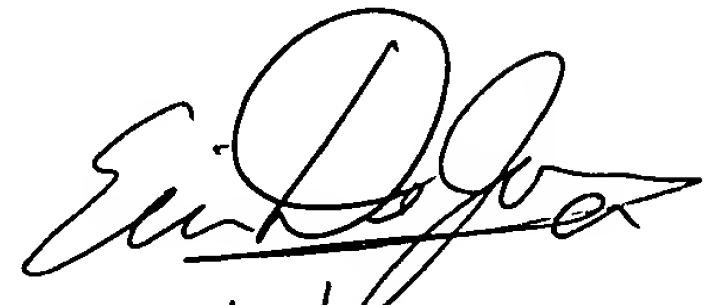
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Moran Marjorie can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong  
Examiner  
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08/31/2007